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**Subject:** **Docket No. 2003N-0324 and RIN 0910-AC35**
**Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products**

Wyeth Consumer Healthcare ("WCH") is submitting comments in response to FDA's April 22, 2004 *Federal Register* publication of a proposed rule for a Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products. These comments pertain specifically to labeling for OTC drug products impacted by the rule. WCH opposes the placement of an additional toll-free number on labeling for OTC NDA/ANDA products and requests FDA re-consider the proposal. WCH is aware of the requirements of the "Best Pharmaceuticals for Children Act" and requests that if the FDA proceeds with requiring placement of the 1.800.MedWatch number on OTC products, FDA address the points identified in this letter, and those points communicated to the FDA by the Consumer Healthcare Products Association.

WCH considers the proposed rule to be inappropriate for OTC drugs for the following reasons:

- **Addition of safety contact information is neither necessary nor appropriate for OTC drug products.**

The Best Pharmaceuticals Children Act correctly and appropriately addresses the need to have safety contact information available to the consumer, however, it should be interpreted to apply only to prescription products that typically lack a telephone contact number. Over-the-Counter products are already regulated by 21CFR201.66(c)(9), which allows manufacturers of OTC NDA to include telephone contact information on product labeling. Since most companies take advantage of that option, a requirement to add a second number will likely result in confusion for the consumer. Adverse event information collected by the manufacturer through this method is routinely reported to FDA in Periodic Safety reports and/or expedited reports as specified by existing regulations.

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- **The proposed rule will interfere with collection and analysis of adverse event reports by the manufacturer and does not ensure that manufacturers are notified in a timely manner.**

A primary source of adverse event reports for WCH is the consumer telephone number. The proposed rule does not define how FDA will notify manufacturers of adverse event reports received through the proposed 800 number that associated with their own products. Any delay between when FDA receives a report and when the manufacturer is able to obtain it from FDA is problematic. This is especially important in the case of a serious event, where the manufacturer may need to take immediate action to protect consumers. In addition, if the proposal is adopted, it is likely that the majority of adverse events will be reported to FDA rather than the manufacturer. Since NDA holders are required to perform benefit/risk assessments, data collection by FDA (without timely release of all information by FDA to manufacturers) will hamper the sponsor with on-going practice of regular benefit/risk assessment. In addition, when FDA communicates adverse event information back to the manufacturer, they will need to change their regulations. Currently, FDA can only send anonymized records that exclude the reaction description.

- **The proposed rule will result in FDA receiving adverse event reports from consumers not residing in the US.**

FDA should define how they would handle reports phoned in from consumers not residing in the US. Some US labeled product is exported to other countries. Currently when we receive reports from sources worldwide we report them to each country as required by each country's laws and regulations.

- **The proposed rule does not specify how FDA will differentiate safety reports from reports with quality issues and how FDA will handle quality reports.**

FDA must define how they will differentiate safety reports from reports that include quality issues; what actions FDA will take with regards to quality reports it receives, and how FDA will handle reports that have both quality and safety aspects. There is no method provided to notify manufacturers of quality issues, hence companies may not learn about quality related issues early enough to take the relevant action and follow-up. The Final Rule should explain how and when FDA would notify manufacturers of quality issues in a timely manner so that manufacturers can take appropriate action.

**The proposed rule does not specify that FDA will redirect calls for general information.**

Consumers call OTC drug manufacturers for a variety of reasons, only one of which is to report an adverse event. In contrast to Rx products, under the proposal OTC products would have two phone numbers on their labels: the FDA's number for "side effects" and the manufacturer's number for "questions or comments". Consumers may not know what constitutes a "side effect" and thus would be confused about which toll-free number to call, the manufacturer's number or the FDA's number. As a result, FDA will be burdened by many spurious reports that often have nothing to do with safety, reports that manufacturers now receive via their own toll-free numbers. This will be a great inconvenience to consumers, as they would in some cases have to call FDA as well as the manufacturer. Also, consumers would not know who is taking action on their report. Currently, if a consumer contacts the manufacturer, all their needs are met by one party. FDA must plan on maintaining a list of all OTC products with the correct manufacturer complaint number to provide to consumers who have called the wrong number.

- **The proposed rule does not define how FDA will reconcile duplicate reporting.**

The Final Rule will result in double reporting of adverse events. It is conceivable that the AE may be reported to FDA first by the consumer to report the "side effect" and again by the manufacturer after the consumer contacts the manufacturer (for other issues unrelated to safety concerns). As a result, with the limited information provided, it will be difficult to reconcile or account for potential double reporting.

- **The proposed rule creates an inconsistent approach to adverse event reporting for NDA vs. monographed products.**

The proposed rule as written applies to NDA and ANDA OTC drugs only. This creates an inconsistency with OTC monograph drugs that would not carry the FDA toll-free number for adverse event reporting. As some OTC ingredients are present in both NDA/ANDA drugs as well as monograph drugs (i.e., chlorphenriamine), monitoring their safety should be important regardless of the regulatory status of the product.

- **The proposed rule does not address how FDA will assist us with Part 11 compliance activities.**

Manufacturers are required to comply with Part 11, where as FDA is not. When FDA communicates adverse event information back to the manufacturer, integrity of FDA data must be ensured in order for manufacturers to maintain Part 11 compliance.

- **The proposed rule does not address how problems with timely release of AERs data will be resolved.**

FDA has been experiencing problems with releasing AERS data extracts. The most current release, which we received within the past two weeks, includes data up to third quarter of 2003. Since 1997, timing for release of AERS data has not been optimal. Also, FDA has been changing the structure of the database that they release requiring the manufacturers to revise our database system to accommodate the changes.

In conclusion, based on the above points, WCH opposes the placement of an additional toll-free number on labeling for OTC NDA/ANDA products and requests FDA re-consider the proposal. Any requirement for adding safety contact information should be implemented with a comprehensive system for collecting and communicating safety information that includes the manufacturers. Any contact information or system for managing safety reports must address the outcome of implementing such a requirement that is consistent with the objective of the Best Pharmaceuticals for Children Act, and does not stop with the simple addition of a telephone number.

Sincerely,
WYETH CONSUMER HEALTHCARE

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